REMARKS/ARGUMENTS

Claims 1 through 29 were pending. Claims 17 and 18 were examined and rejected, with the remaining claims having been withdrawn pursuant to an election of species requirements. The claims have been amended and new claims added as noted above. Reexamination and reconsideration of the claims, as amended, are respectfully requested.

Applicants have cancelled claims 1-16 and 24-29 which were not designated to correspond to the elected species. Applicants note that new claims 30-44 correspond to cancelled dependent claims 2-15. While these claims reflect certain aspects of a non-elected species, it is noted that they are now dependent on generic claim 17. As generic claim 17 is allowable for the reasons discussed in detail below, examination of these dependent claims to a non-elected species is appropriate.

Independent claim 17 and claim 18 dependent thereon were rejected as being anticipated by the Makower '562 publication. Such rejections are respectfully traversed.

Independent claim 17 is directed at an intravascular drug delivery method where "a delivery aperture of the needle has penetrated into tissue beyond an external elastic lamina (EEL) of the blood vessel before injecting the pharmaceutical agent." Nowhere does Makower '562 ever describe or suggest that a needle must be penetrated beyond the EEL of a blood vessel. While Makower does disclose that the needles are penetrated "outwardly" and "through" the blood vessel wall, nowhere is there any teaching or suggestion that penetration must extend beyond the EEL. Thus, there is no teaching and no motivation which would suggest the central step of claim 17 herein, i.e., that the position of the needle delivery aperture beyond the EEL be confirmed.

Nor does Makower '562 teach or suggest using a contrast medium to confirm the position of a delivery aperture of a needle. The Examiner relies on paragraph 93 which reads as follows:

> *"[0093] The present invention allows for mapping or assessment of the site at which the delivery catheter 12 is positioned to confirm that the site is, or continues to be, suitable for the intended purpose. For example,* ***a radio-labeled compound, radio-isotope or other traceable substance*** *may be introduced through the delivery catheter and* ***the rate at which the radio-labeled substance or isotope distributes away from the injection site may be measured*** *by well known techniques. If the distribution away from the site is determined to be too rapid or too slow, the delivery catheter 12 may be repositioned before the desired therapeutic or diagnostic substance is injected. In chronic dosing applications wherein the delivery catheter 12 remains indwelling for days or months, this technique may be used to ensure that the delivery catheter 12 has not migrated or moved from the intended injection site, or that the site has not become excessively vascularized since delivery of the last dose. In some applications, it may be desirable for the delivery catheter 12 to have multiple lumens, such that the desired therapeutic or diagnostic substance or apparatus may be delivered through one lumen and a traceable substance useable for mapping or assessment of the target site may be delivered through another lumen."*

As can be seen from the bolded passages in paragraph 93, Makower '562 at best teaches that a radio-isotope or radio-labeled substance be introduce through a needle and that the rate at which the isotope distributes away from the injection site be monitored. It is respectfully pointed out that a radio-isotope is not the same as or equivalent to "contrast media" as set forth in dependent claim 18. Such contrast media, which could be fluoroscopic, ultrasonic, or the like, requires that the media be visible under the relevant imaging protocol. Moreover, it is neither taught nor obvious how monitoring how the "rate" at which the substance is dissipated would tell the treating physician whether or not the aperture of the needle has been positioned beyond the EEL, as required by claims 17 and 18 herein.

For these reasons, the stated rejection for anticipation must fail. Moreover, there would be no reason or motivation to modify the teachings of Makower '562 in such a way that an obviousness rejection could be supported.

Applicants have submitted a Terminal Disclaimer over copending application 11/365,309 over the provisional Double Patenting rejection. Finally, it is noted that new dependent claims 29-34 are neither taught by nor remotely suggested by the teaching by Makower '562.

In view of the above amendments and remarks, applicants believe that all pending claims are in condition for allowance and request that the application be passed to issue at an early date.

If for any reason the Examiner believes that a telephone conference would in any way expedite prosecution of the subject application, the Examiner is invited to telephone the undersigned at (650) 326-2400.

Respectfully submitted,

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